

K871634 CLEARFIL FII NEW BONDJul 17, 1987
81 days to decisionK871634 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k871634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 27, 1987
Decision date	Jul 17, 1987
Days to decision	81 days
Third-party review	No

APPLICANT

Company	Kuraray Co.
Location	New York, NY, US
Contact	PAUL ROBERTS
510(k) history	25 submissions · 25 cleared · 1985-1999

Kuraray Co. is a Japanese manufacturer of chemicals, fibers, and advanced materials. The company maintains a US presence through its New York office. Kuraray received FDA 510(k) clearances from total submissions, with all submissions focused on Dental devices. The company's regulatory activity spans from 1985 to 1999, establishing a historical record in dental bonding and restorative materials. The cleared devices reflect Kuraray's specialization in dental adhesive systems and bonding technologies. Products include resin cements, surface activators, and liner bond systems...
